LD011
P-111380.00
MCS

Medtronic

INVENTION DISCLOSURE FORM

WARNING: Due to the confidential nature of this document, save it as a password protected document. Do not send this document through GroupWise.

This is a WORD Template form. Press enter or tab to move to each field. Please fill out this form as completely as possible. If the allotted space is not sufficient, use a separate sheet. Have your manager sign the form and forward it to the Patent Section of the Law Department, MS301. Please attach any drawings and technical descriptions that are available and assemble copies of the background articles, books, advertisements, etc. for use by your patent attorney.

1.

Inventor(s) Full Name(s)	Employee Number	Mail Stop	Home Address (Include Zip Code)	
Douglas Stephen Hine	13745	B230	3647 Willow Lane White Bear Lake MN 55110	
John Louis Sommer	2380	B252	12788 Ibis Street NW, Coon Rapids, MN 55448	
Dr John Gurley	N/A	N/A		

2. Title of Invention: Pacing lead with multiple electrodes having one IS-1 compatible connector pin

3. Summary of the Invention: This invention covers a pacing lead design with mutliple electrodes on a lead having one connector pin that fits into any IS-1 header cavity. This invention offers mulitple pacing and sensing options (selectable electrodes) with various polarity configuations for programming a device for optimal threshold performance, optimal sensing performance, eliminating phrenic nerve stimulation, or optimizing device therapy. An electrode pair is selected at implant during routine pacing tests (threshold, sensing, phrenic nerve stim) by using alligator clips on two of the four exposed connector rings. The connector pin is smaller in diameter than IS-1 and segmented such that each of the four exposed rings is connected to a distal electrode. Once a pair is selected, a metallic cap (IS-1 size) is placed over the smaller segmented connector pin. When the cap is placed over the segmented pin, it insulates two of the segments and makes electrical contact with the other two segmented rings. This creates a biploar arrangment. The metallic IS-1 cap can be removed at a later date and replaced with a different IS-1 cap to "select" a different bipole. Before today, this could not be done with one IS-1 compatiblle connector pin. This could have multiple applications including left heart right heart and epicardial pacing systems.

4. How have others addressed this problem (List and attach any patents, books, articles, devices, Medtronic or competitor's products, or other background materials you used or which may be prior art)? Guidant has done studies on multi polar LV electrode design. However, it appears to be an acute study only without IS-1 compatibility. This could be done using a split connector having two IS-1 connectors.

5. The invention is described on pages 7-10 of Lab Notebook No. 10672 (Please attach copy).

6. When was a device built which included the invention? NA

   Who built it? NA Where is it? NA

   Who has supporting documents? NA

   Who witnessed tests? NA When and where? NA

7. Discuss the problems which the invention is designed to solve, referring to any prior devices of a similar nature with which you may be familiar. This concept addresses the issue

8. State the advantages of the invention over presently known devices, systems or processes. This invention allows one lead to be used with one connector pin that fits into any IS-1 header. This allows universal use of a selectable bipole lead with todays pacing systems. No change to the pacing generator header or circuitry is needed.

9. List all known and other possible uses for the invention. Pacing and sensing, including left heart, right heart, epicardial leads.

10. Specifically describe the invention and its operation. You may use and attach copies of sketches, prints, photographs and illustrations which should be signed, witnessed and dated. Use numbers and descriptive names in descriptions and drawings. See attached lab notebook pages.

EXHIBIT B

11. List all features of the invention that a[illegible] believed to be novel. Selectable electrodes on [illegible] lead having one IS-1 compatible connector pin. An IS-1 connector pin cap that can be placed over a segmented pin that allows selectable electrodes at implant or during repositiong.

12. Sale or Publication (Needed to establish the date of any printed publication, public use or sale, since no U. S. patent application may be filed after one year from such date.)

a. If a device has been offered, or will be offered for sale, or used for profit or otherwise publicly disclosed, state when and to whom delivered and how used? _____

b. Has a printed description of this invention been made available to persons outside the company? How and when and was use restricted (e.g. licensing agreement, non-disclosure agreement, proprietary legends, etc.)? Dr. John Gurley is a co-inventor. It was discussed with him on July 9, 2002 at an offsite meeting.

13. ~~Inventor(s)~~ Signature(s) (REQUIRED):

[signature]	29 July 02
Signature	Date
John L Sommer	15 Oct 02

Manager's Comments

14. How is this invention important to your products, plans or goals?

OR MULTIPLE ELECTRODE
MULTIPOLAR ^ CONFIGURATIONS MAY PLAY AN IMPORTANT ROLE IN HF - CRT IN THE NEAR & LONG TERM FUTURE. THIS INVENTION ALLOWS SELECTION OF POLARITY CONFIGURATIONS W/O CHANGES TO DEVICE

15. Manager's Signature (REQUIRED)

Jack Germanson	31 OCT 02
Signature	Date

Manager's Printed Name Jack Germanson

Mail Stop B230

Business Unit Cardiac Rhythm Management Therapy Delivery

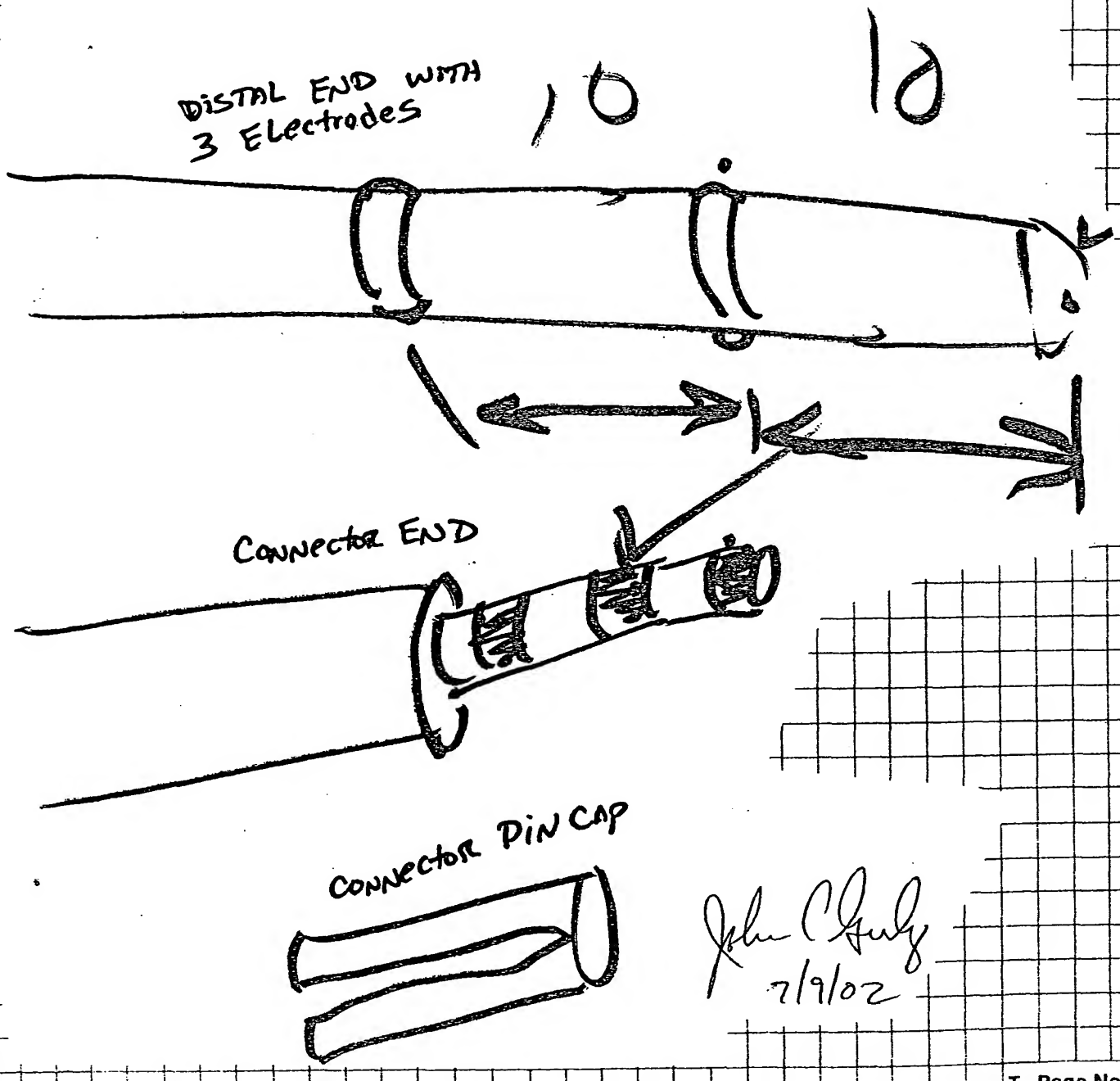
Manager: Please forward to Patent Section of Law Department, MS 301, upon completion of your review.

Project No.

TITLE Pacing LEAD WITH Multiple Electrodes having ONE IS-1 Compatible connector Pin

Book No. 10672

From Pag No.



John C Gurley
7/9/02

T Page No.

Witn ss d & Understood by m ,	Date	Invented by	Dat
		Record d by	15Jly02

From Page No. 1

Purpose: TO INVENT A LEAD WITH Multiple electrodes at its DISTAL Tip. A multi-conductor coil, WITH EACH FILAR Independently INSULATED IS USED to connect the electrodes TO ONE termination pin. This pin IS SEGMENTED SUCH THAT ANY pair OF electrodes CAN be selected AND tested FOR PACING AND SENSING. ONCE AN OPTIMAL pair IS FOUND. A Metallic IS-1 CAP IS PLACED OVER The SEGMENTED termination pin. This CAP will be IN electrical CONTACT WITH TWO OF The SEGMENTS OF The termination pin while INSULATING The other TWO SEGMENTS.

Benefit: This INVENTION ALLOWS the physician TO Select ONE electrode pair THAT provides The optimal PACING performance, eg. Good THRESHOLDS for PACING, Good SENSING, No Phrenic Nerve STIMULATION AND optimized CARDIAC Resynchronization Therapy. This design ALLOWS A Multiple electrode LEAD to be "SelectAble" While still being IS-1 Compatible

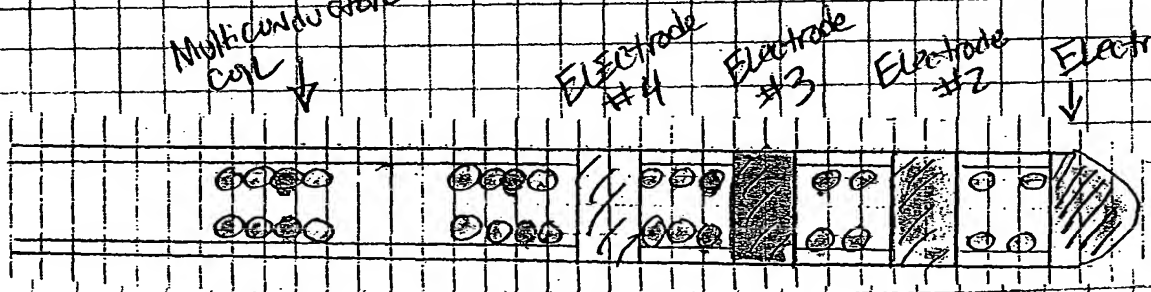


FIGURE 1, DISTAL Tip of Multi-electrode lead

To Pag No.

Witnessed & Understood by me,	Date	Invented by DoAH	Date 18 July 02
		Recorded by	

PACING LEAD WITH Multiple Electrodes Project No.
TITLE having one IS-1 Compatible connector pin Book No. 10672 9

From Page No.

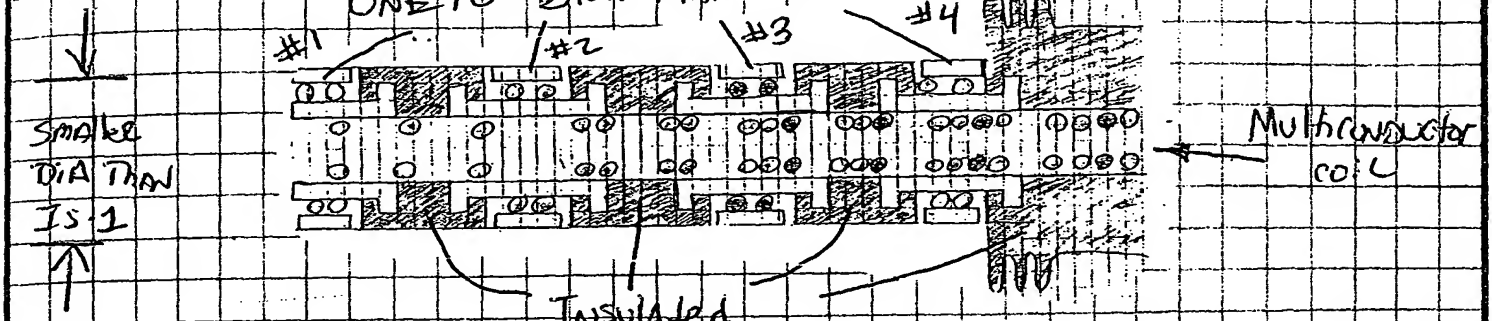
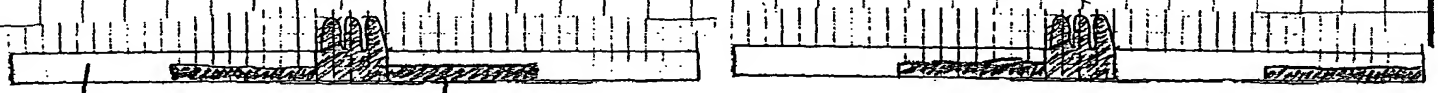
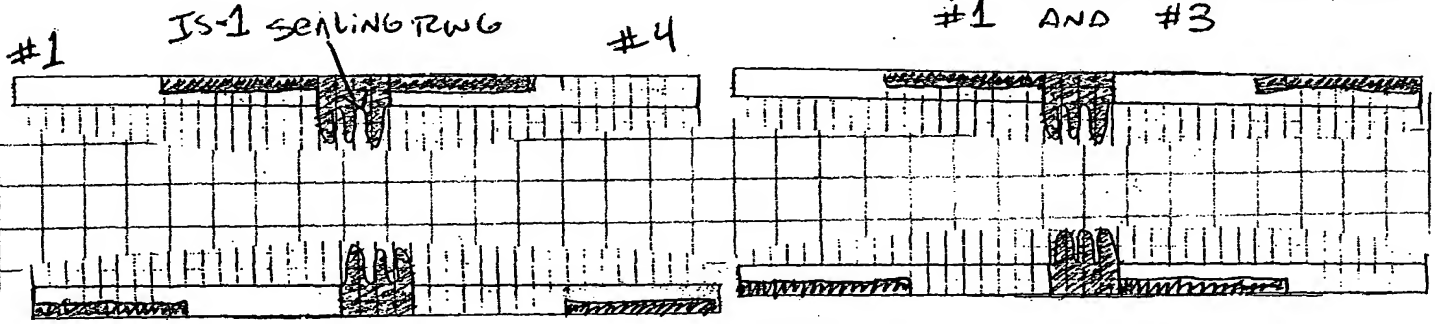


FIGURE #2. SEGMENTED termination pin

CHOSING ONE OF THE FOLLOWING IS-1 termination pin CAPS WILL PROVIDE THE desired electrode PAIR. FOUR combos ARE POSSIBLE AS shown below.



THIS CAP ACTIVATES electrode pair #1 AND #3



This Cap Activates electrode pair #2 AND #3

This CAP ACTIVATES electrode pair #2 AND #4

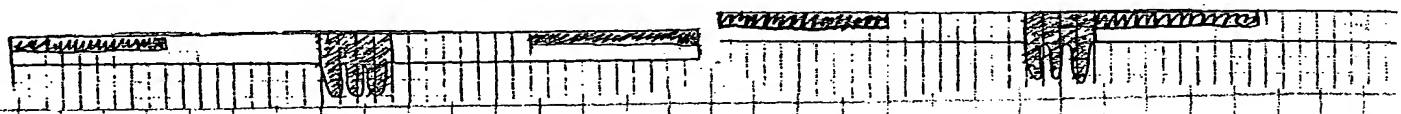


FIGURE 3. Metallic IS-1 CAPS. EACH CAP will PROVIDE A DIFFERENT electrode pair TO be ACTIVE

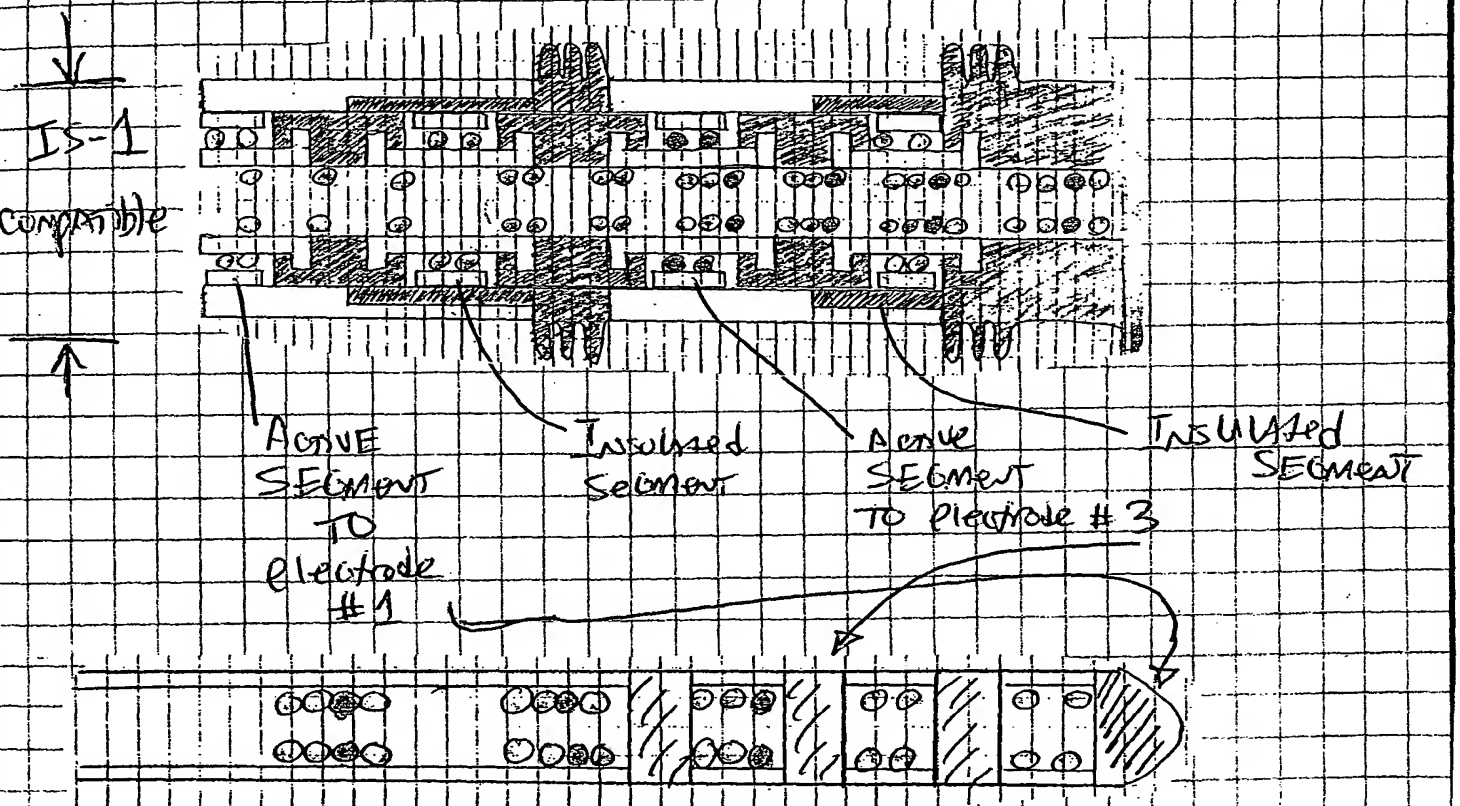
To Page No.

Witnessed & Understood by me,	Date	Invented by D.A Ido	Date 19July 02
		Recorded by	

From Page N

Once the IS-1 connector pin cap is ~~slide~~ DN (BOS) slid over the segmented connector pin two of segments are insulated while two of the segments make contact with the metallic pin cap.

This assembly is now properly sized for any IS-1 compatible generator. It will functions as a bipolar lead without any changes required to standard IPG header or circuit design.



IF A different bipole is required after implant, the IS-1 connector pin cap can be exchanged for a different one which selects an alternate bipole. Four pairs are possible unless the IPG can be programmed to "Reverse polarity" in which eight options are available

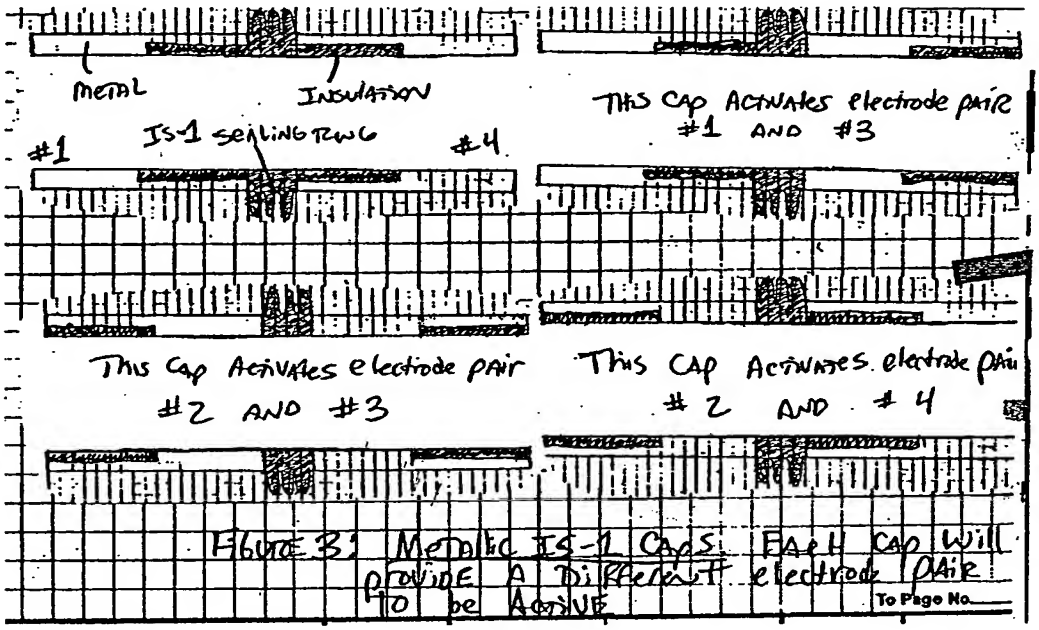
To Page No.

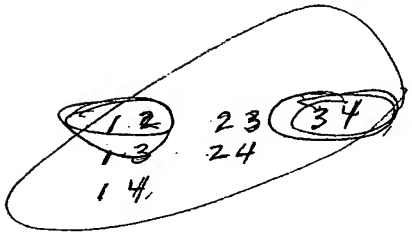
Witnessed & Understood by me,	Date	Invented by B. A. H.	Date
		Recorded by	19 July 02

CRM Leads Patent Review Board
December 10, 2002

P-11138 "Pacing Lead With Multiple Electrodes Having One IS-1 Compatible Connector Pin" Hine, Sommer, Gurley

Describes an adaptor cap which selects an anode to be used with multi-anode leads. The cap allows the lead to be used with an IS-1 connector.



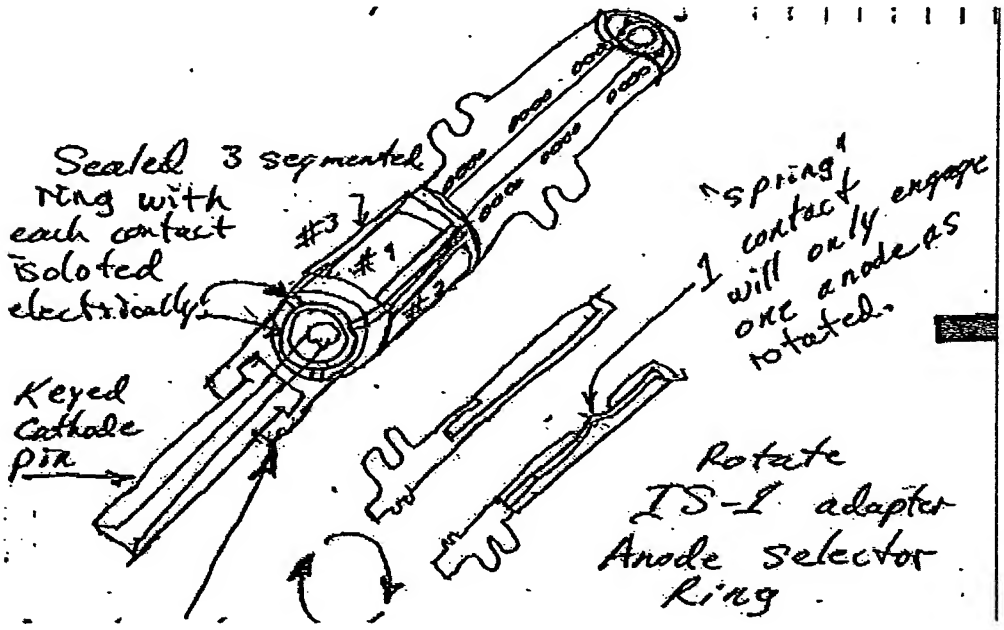


P-11138 continued

Prior Art

1. P-11139 "Selectable Electrical Connection" Sommer, Hine

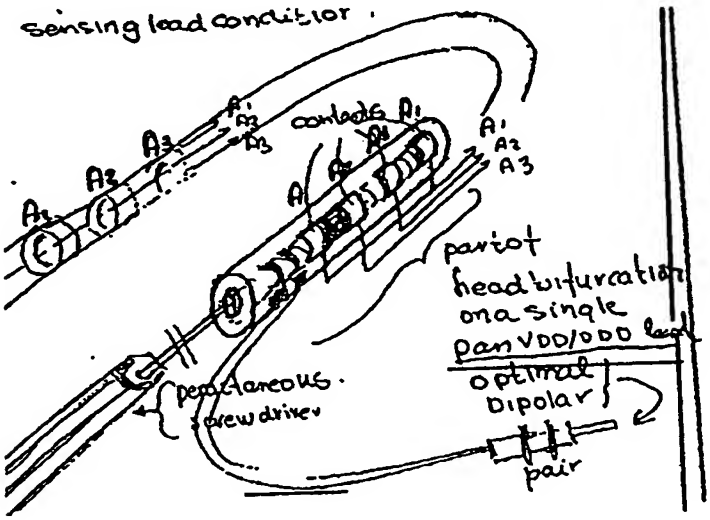
   Describes an IS-1 adaptor which uses a spring-mounted contact to select between multiple anodes on a lead. This allows multi anode leads to be used with a standard IS-1 connector block.



P-11138 continued

2. P-3563 "A Percutaneous Switch To Select Optimal Sensing Lead Conditions" Bakels et al

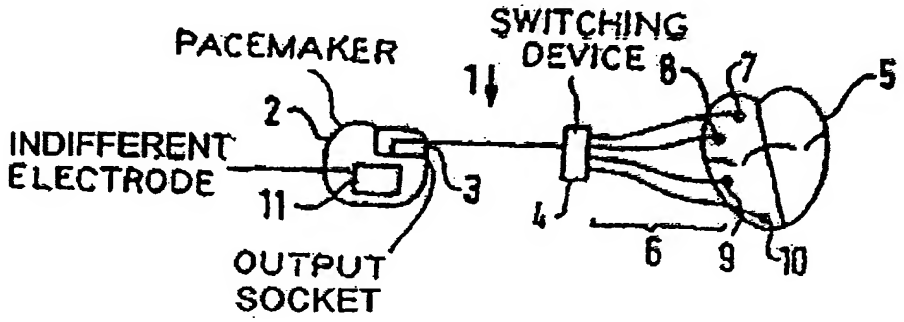
Percutaneously adjustable rotating cam selects bipolar lead connections from multiple atrial electrode.



P-11138 continued

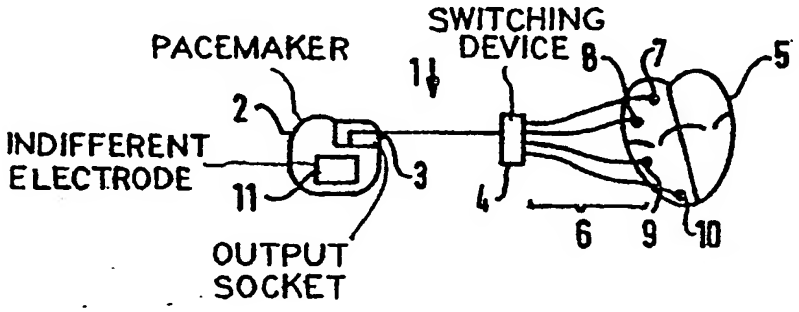
3. P-4227 "Intermediate In-Line Programmable Multi-Channel Selector For Multi-Site Sequential Pacing" Struble

A multichannel selector is disclosed that controls/directs pacing stimulus to the correct lead system. Device is incorporated between pacer and lead systems.



4. 5,423,873 "Device For Stimulating Living Tissue" Neubauer et al (Siemens Elema AB)

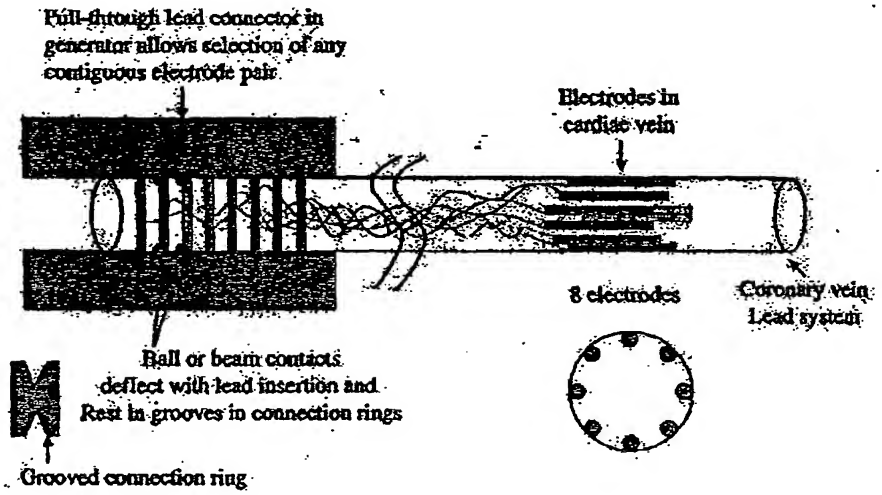
Describes a programmable switching device placed between the IPG and lead.



P-11138 continued

5. P-9797 "Focused Delivery Coronary Venous Electrode" Duffin, Brostrom

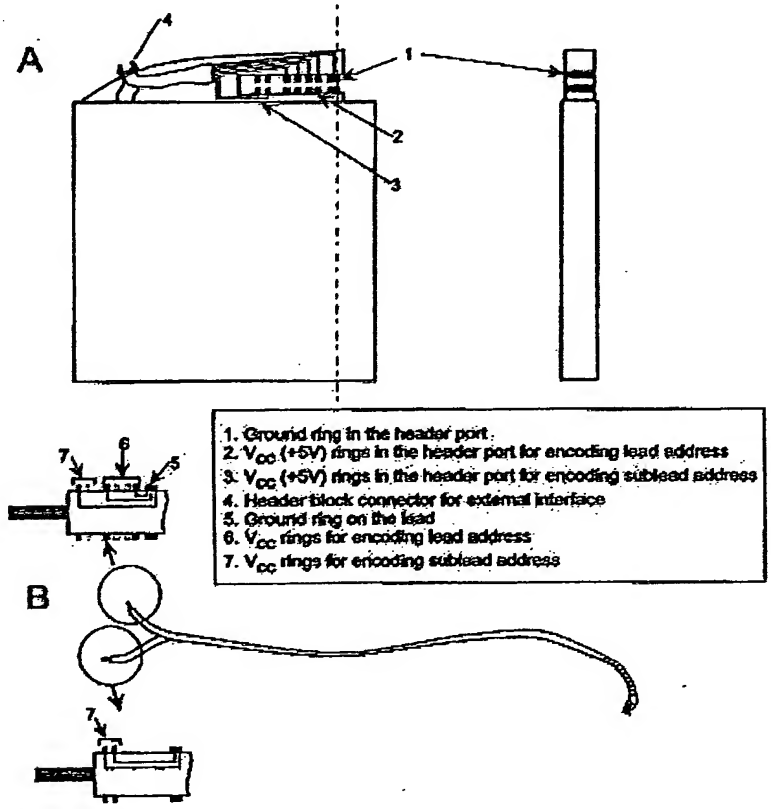
Connects an output circuit to a selected pair of electrodes chosen by the position of the lead connector pin within the connector block.



P-11138 continued

6. P-9569 ""Automatic Lead Identification System for ICDs" Sharma, Whitman, Bonner

Lead identification based upon a unique binary code set via proximal lead ring electrodes.



P-11138 continued

7. P-9124"Multiple Electrode-Array with Incorporated Switch to Select Stimulation Site" Heynen, Lokhoff, Houben

Epicardial electrode array that may have electrode configuration selected/controlled by a coded signal from an implanted device or external box.